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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/998,766 | 11/29/2001 | Patrick J. Duane | P1036 US | 6469 |

7590 10/01/2004
IP Legal
Medtronic AVE, Inc.
3576 Unocal Place
Santa Rosa, CA 95403

EXAMINER

HO, UYEN T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 3731 | |

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|--|--|--|
| <p align="center">Office Action Summary</p> | Application No. 09/998,766 | Applicant(s) DUANE, PATRICK J. | |
| | Examiner (Jackie) Tan-Uyen T. Ho | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 18, 20, 23 and 24 is/are rejected.
- 7) ☒ Claim(s) 16, 19, 21, 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's arguments filed 7/19/04 have been fully considered but they are not persuasive. Applicant argues that Daniel et al. fail to teach a self-expanded open configuration. Examiner respectfully disagrees. The tubular 254 at the position as shown in figures 18B, the filter member 250 having a self-expanded open configuration such that the member 262 does not collapse onto the guide wire 252 or onto the tubular member 254 and wherein axial displacement of the proximal open apex towards the distal open apex (figs. 18C) reversibly transforms the protection element/filter (250) from the open configuration to the closed configuration (fig. 18D).

The broadest reasonable interpretation of "the protection element comprising a self-expanded open configuration" encompasses an element retaining its opening configuration by itself in at least one position.

Applicant argues that Daniel et al. do not teach the utility of positioning a distal portion of an inflated balloon within a protection element as required by claim 2. Examiner respectfully disagree. Claim simply recites the inner body of the protection element is shaped as such when the protection element is in the open configuration it can receive a distal portion of an inflated balloon. The functional limitation "to receive a distal portion of an inflated balloon of an interventional catheter" has been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the shape of Daniel's filter which is capable of being used as claimed if one desires to do so. Note: the limitation "a distal portion of an inflated

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balloon of an interventional catheter" within the protection element is not positively claimed.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 4, 8, 12-15, 17, 18, 20, 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniel et al. (5,814,064).

Daniel et al. disclose a distal protection apparatus, as claimed comprising: a shaft (252), protection element (262) having a ring portion (270), a conical braided outer body and a conical braided inner body (figures 18B-18D), a closed configuration, as claimed (figure 18D), and an open configuration, as claimed (figure 18B, C).

The introductory statement of intended use and all other functional statements have been carefully considered but are deemed not to impose any structural limitations on the claims distinguishable over the Daniel et al.'s device which is capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 2, 5-7, 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. '064. In regard to claim 2, although, Daniel et al. do not disclose an inflated balloon, it is known in the art that an inflated balloon is couple to a distal protection device for treating a stenosis. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an inflated balloon into the Daniel et al.'s distal protection apparatus in order to treat the stenosis (26, figure 1) as disclosed in Daniel et al. reference.

In regard to claims 6, 7, 9-11, although, Daniel et al. do not disclose a flexible structure for supporting the filter material, it is known in the art to have flexible structure, a wire-like struts in order to provide a support for the filter material and to optimize the open or close configuration of the filter material. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a flexible structure, a known wire-like struts in the art into the Daniel et al.'s distal protection apparatus in order to provide a support for the filter material and to optimize the open or close configuration of the filter material.

Allowable Subject Matter

6. Claims 16, 19, 21 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 703-308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731
September 20, 2004


ANH TUAN T. NGUYEN
PRIMARY EXAMINER

9/29/04.